

Remarks

Claims 35-39, 47, 51, and 56 are pending in the subject application. Applicants acknowledge that claims 51 and 56 have been withdrawn from further consideration as being drawn to non-elected invention. By this Amendment, Applicants have canceled claims 38, 47, 51 and 56, amended claims 35 and 39 and added new claims 57-94. Support for the amendments and new claims can be found throughout the subject specification and in the claims as originally filed (see, for example, the original and previously presented claims, pages 9-10 of the as-filed specification and Example 2). Entry and consideration of the amendments presented herein is respectfully requested. Accordingly, claims 35-37, 39 and 57-94 are currently before the Examiner. Favorable consideration of the pending claims is respectfully requested.

Claims 35-39 and 47 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The Office Action states that SEQ ID NOs: 6, 8 and 13 (*i.e.*, a peptide sequence between 5 and 10 amino acids that binds to OX40R, an active mutant or fusion proteins or derivatives containing them) do not have adequate written description.

An objective standard for determining compliance with the written description requirement is, “does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed.” *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989). Under *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed. It is respectfully submitted that Applicants have met this test given the teachings of the specification and the scope of the claims.

In the case of the claimed invention, the claims recite polypeptides consisting of a defined number (31 or fewer) of contiguous amino acids of human OX40 ligand (OX40L). These peptides consist of: amino acids 94-124 of OX40L; amino acids 94-124 (SEQ ID NO: 6) wherein one or more amino acids have been deleted, the peptide contains amino acids 107-111 (SEQ ID NO: 13)

and the peptide binds to the OX40 receptor (OX40R); between 5 and 10 contiguous amino acids of OX40L, wherein said peptide contains amino acids 107-111 (SEQ ID NO: 113) and binds to OX40R; amino acids 107-116 (SEQ NO ID: 8) or 107-111 (SEQ ID NO: 13) of human OX40L; or active mutants of the aforementioned peptides, wherein one or more of the amino acids has been conservatively substituted and said active mutant binds to OX40R. The as-filed specification indicates that the OX40R binding portion of the disclosed peptides is associated with amino acids 107-111 of SEQ ID NO: 13 (see Example 2, page 36, lines 11-15 and Figure 6). Further, the as-filed specification discloses a number of peptides having the recited characteristics (see Example 2). Additionally, the as-filed specification (at pages 9-10) provides teaching as to substitutions that can be made within the claimed peptides and methods of screening the peptides for activity (OX40R binding) are also disclosed in the application. Applicants also note that the term “active” is defined in the as-filed specification as a compound demonstrating the OX40R binding properties of the peptides disclosed within the as-filed application (see page 9, lines 9-10). Finally, the as-filed specification provides teachings as to the peptide mimetics to be designed upon the sequences disclosed within the as-filed specification (see pages 15-16). Thus, it is respectfully submitted that there is adequate written description in the subject specification to convey to the ordinarily skilled artisan that they had possession of the claimed invention. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, first paragraph, is respectfully requested.

Claims 35-39 and 47 are rejected under 35 U.S.C. § 112, second paragraph, as indefinite. Applicants respectfully submit that the claims are definite and that one skilled in the art, in view of the teachings of the as-filed specification, would be able to ascertain the metes and bounds of the claimed invention. However, in the interest of advancing prosecution in this matter, the claims have been amended to resolve the issues raised in the Office Action. For example, the issue raised with respect to part c) of claim 35 has been redrafted to indicate that the peptide sequence of human OX40L is between 5 and 10 contiguous amino acids, that the peptide contains amino acids 107-111 of the OX40L and that the peptide binds to the OX40R. With respect to the parentheticals, it is respectfully submitted that, in view of the specification, one skilled in the art would recognize that the SEQ ID NOs: identified within the parentheticals refer to amino acid subsequences of the OX40L (see, for example, Table 3, Figure 6 and other portions of the as-filed specification). Again,

however, the parentheticals have been canceled in an effort to advance prosecution in this matter. Turning to the rejection as relates to the term “derivative”, it is respectfully submitted that the metes and bounds of the claimed invention is clearly set forth, particularly in view of the teachings of the as-filed specification at page 14, lines 6-11. The issues raised with respect to claims 38 and 39 are now moot in view of the amendments made to the claims. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, second paragraph, is respectfully requested.

Claims 35-39 and 47 are rejected under 35 U.S.C. § 102(b) as anticipated by Godfrey *et al.* (U.S. Patent No. 6,242,566). The Office Action states that the Godfrey *et al.* reference teaches purified ACT-4-L ligand polypeptides; an exemplified ACT-4-L ligand designated ACT-4-L-h-1. The Office Action further states that SEQ ID NO: 6 of the subject application is 100% identical with the amino acid string 94-124 of SEQ ID NO: 4 of Godfrey *et al.*

Claims 35 and 36 are rejected under 35 U.S.C. § 102(b) as anticipated by O’Hare *et al.* (U.S. Patent No. 6,017,735). The Office Action states that O’Hare *et al.* teach coupled fusion proteins for intracellular transport, that include an amino acid sequence with the transport function of herpesviral VP22 protein and an immunomodulating protein sequence (abstract).

Claims 35 and 39 are rejected under 35 U.S.C. § 102(b) as anticipated by Godfrey *et al.* (1994). The Office Action asserts that Godfrey *et al.* disclose the human OX-40 ligand, which comprises in its sequence the SEQ ID NO: 6 of the subject application.

Claims 35, 36 and 47 are rejected under 35 U.S.C. § 102(b) as anticipated by Weinberg *et al.* (U.S. Patent No. 6,312,700). The Office Action states that Weinberg *et al.* teach a fusion between OX-40L extracellular domain and a polypeptide representing a constant domain of human IgG, particularly the CH2 and CH3 domains of IgG.

Applicants respectfully assert that none of the cited references anticipate the claimed invention because the claimed polypeptides are limited, in length, to amino acids 94-124 of the OX40L, subsequences thereof or fusion proteins that are a non-OX40L sequence fused to a peptide consisting of amino acids 94-124 of the OX40L or subsequences thereof. Applicants have reviewed each of the cited references and have been unable to identify any teaching of peptides meeting the limitations of the claims. Accordingly reconsideration and withdrawal of the rejections under 35 U.S.C. § 102(b) is respectfully requested.


It should be understood that the amendments presented herein have been made solely to expedite prosecution of the subject application to completion and should not be construed as an indication of Applicants' agreement with or acquiescence in the Examiner's position. Applicants expressly reserve the right to pursue the invention(s) disclosed in the subject application, including any subject matter canceled or not pursued during prosecution of the subject application, in a related application.

In view of the foregoing remarks and amendments to the claims, Applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

Applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



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